

510(k) SUMMARY

SEP 26 2011

Submitter Information: TOTOKU ELECTRIC CO., LTD.
300 Oya, Ueda
Nagano 386-0192 Japan

Contact Person: Tsukasa Tashiro, General Manager
Email: tasirot@totoku.co.jp
Tel: +81.258.24.6611
Fax: +81.258.24.6617

Date Prepared: May 26, 2011

Device Name: 21.3 inch (54 cm) Monochrome Digital Mammography LCD Monitor
MS53i2 (ML21053)

Common Name: MS53i2, ML21053

Classification Name: Class II
(Part 892 Radiology Devices
Sec. 892.2050 Picture Archiving and Communication System)

Predicate Device: 5M Monochrome Digital Mammography LCD Monitor ME551i2
(MDL2116A) (K061447).

Device Description: MS53i2 (ML21053) is a 21.3-inch (54 cm) monochrome LCD monitor whose display resolution is 2048 x 2560 (landscape), 2560 x 2048 (portrait) supporting DVI (digital visual interface).

Indended Use: 21.3 inch (54cm) Monochrome Digital Mammography 5M pixel LCD Monitor with sub-pixel driving techniques enabling 15M subpixels to be driven independently, MS53i2 (ML21053) is intended to be used in displaying and viewing medical images for diagnosis by trained medical practitioners. It is to be used in digital mammography PACS and modalities including FFDM.

Substantial Equivalence: MS53i2 (ML21053) shares the same characteristics with our predicate device ME551i2 (K061447) except for the LCD panel and the power supply.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Mr. Tsukasa Tashiro
General Manager
TOTOKU Electric Co., Ltd
300 Oya, Ude, Nagano 386-0192
JAPAN

SEP 26 2011

Re: K111496

Trade/Device Name: 21.2 Inch (54cm) Monochrome Digital Mammography LCD Monitor
MS53i2 (ML21053)

Regulation Number: 21 CFR 892.2050

Regulation Name: Picture archiving and communications system

Regulatory Class: II

Product Code: LLZ

Dated: August 22, 2011

Received: August 24, 2011

Dear Mr. Tashiro:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

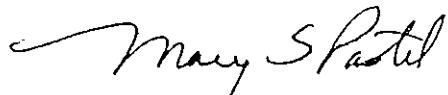
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely Yours,



Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: Not Known

Device Name: 21.3 inch (54cm) Monochrome Digital Mammography LCD Monitor MS53i2
(ML21053)

Indications for Use:

21.3 inch (54cm) Monochrome Digital Mammography 5M pixel LCD Monitor with sub-pixel driving techniques enabling 15M subpixels to be driven independently, MS53i2 (ML21053) is intended to be used in displaying and viewing medical images for diagnosis by trained medical practitioners. It is to be used in digital mammography PACS and modalities including FFDM.

Prescription Use

AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D)

(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S. Pashl
(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
510K K111496